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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,301	10/24/2003	Gary K. Schwartz	702-A-US	1477

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EXAMINER	
MARTIN, PAUL C	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
07/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/693,301	SCHWARTZ, GARY K.	
	Examiner	Art Unit	
	Paul C. Martin	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-38 and 41-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *34,35,38,46 and 47* is/are allowed.

6)☒ Claim(s) *31-33, 36, 37, 41-45 and 48-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 31-38 and 41-50 are pending in this action and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 41, 42 and 48 under 35 U.S.C. § 112, 1st paragraph for not being enabled for the full scope of the claimed invention has been withdrawn due to the Applicant's amendments to the Claims filed 04/26/07.

Claim Rejections - 35 USC § 103

The rejection of Claims 31 and 32 under 35 U.S.C. § 103(a) as being unpatentable over Li *et al.* (2000) is maintained for reasons of record set forth in the prior actions.

The rejection of Claims 31-33, 36, 37, 43, 44, 45, 49 and 50 under 35 U.S.C. § 103(a) as being unpatentable over Li *et al.* (2000) in view of Zhang *et al.* (1990) is maintained for reasons of record set forth in the prior action.

Response to Arguments

Applicant's arguments filed 04/26/07 have been fully considered but they are not persuasive.

The Applicant argues that the response to the Declaration filed 11/27/06 was not directed or pertinent to the rejections under 35 U.S.C. 103(a), e.g. motivation to combine references and reasonable expectation of success, and that the Examiner has not provided any response to the assertion that whether a drug or composition will be useful in clinic can only be determined by vigorous clinical trials (Remarks, Pg. 7, Lines 1-9) and that the Declaration provided numerous examples of drugs that exhibited positive effects *in vitro* which were not ultimately successful *in vivo*.

The MPEP states:

To establish a prima facie case of obviousness, three basic criteria must be met.

First, there must be some *suggestion or motivation*, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a *reasonable expectation of success.* Finally, the prior art reference (or references when combined) must *teach or suggest all the claim limitations.* The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

This is not found to be persuasive for the following reasons, Li *et al.* clearly teaches that cell growth in human cancer cell lines is inhibited by administration an effective amount of aqueous *chinesis* (huanglian) extract comprising the active ingredient berberine, and that huanglian is part of a *known* class of agents that inhibit tumor growth and further suggests the use of huanglian as an oral anticancer drug.

Zhang *et al.* teaches the use of aqueous berberine, in conjunction with a secondary chemotherapeutic agent, as a treatment of solid tumors in rats.

Clearly, the suggestion exists in combining the two references; the first exhibiting successful *in vitro* results of an extract comprising berberine and the second as a successful treatment of cancer *in vivo* in animal models with berberine. In a similar fashion, it is through combination of the two references that all of the claim limitations are taught or suggested as discussed in the prior action. The issue then is whether or not there is a *reasonable expectation of success* that combination of the two references will perform the claimed method. The Applicant's assertion that only clinical data can assess the use of a drug or composition is based upon several examples in the art wherein new drugs or compounds, which were promising *in vitro* failed ultimately in *in vivo* testing.

This argument is not found to be particularly persuasive because, a) these particular compounds are not relevant to the instant extract at hand, they are completely unrelated in both chemical structure, composition and manner of effect, and b) the Applicant has neglected to provide any examples of cancer-treating drugs or compounds which *did* prove successful both *in vitro* and *in vivo*. That these compounds exist is without question as there are in existence, anti-cancer drugs, and it is well known that the pathway to drug development follows the steps of cell culture testing (*in vitro*), animal model testing (*in vivo*) and finally human trials (*in vivo*). The instant references provide teachings of successful inhibition in human cancer cells using the claimed extract, a suggestion to use the claimed extract as an anticancer agent and the use of the active ingredient of the extract to treat cancer *in vivo*. The Examiner maintains that based upon the teachings of the references one of ordinary skill in the art would have a *reasonable* expectation of success in treating cancer..

Conclusion

Claims 34-35, 38 and 46-47 are free of the art and are allowed, Claims 31-33, 36, 37, 41-45 and 48-50 remain rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

6/28/07

JON WEBER
SUPERVISORY PATENT EXAMINER